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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,611	05/04/2001	Andy Swenson	10265.96.1	9485

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,611	SWENSON ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination, Request for Extension of Time and Amendment filed 10/06/03, and Statement of Substance of Interview filed 11/17/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/03 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 7-11, 21, 29 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Bertini et al. US 6,069,172.

Bertini teaches a pharmaceutical preparation for oral administration comprising ketoprofen (see abstract). The preparation in the form of controlled release, slow-release, or immediate release comprises powdered cellulose, maltodextrin, and carboxymethyl cellulose starch (column 10, lines 1-48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7-11, 21, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al.

Bertini is relied upon for the reason stated above. Bertini does not teach that the cellulose and the maltodextrin slow the disintegration of the orally administered specimen to provide a sustained release of the bioactive substance. However, where the claimed and prior art products are identical or substantially identical in composition, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Therefore, it is the

position of the examiner that it would have been obvious for one of ordinary skill in the art to modify the orally administered dosage form of Bertini to obtain the claimed invention, because products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In this case, Bertini teaches the use of mixture of maltodextrin and cellulose in an oral dosage form.

Claims 21-23, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al., and Baichwal et al. US 5,128,143.

Bertini is relied upon for the reason stated above. Bertini does not teach the sustained release time period.

Baichwal teaches sustained release excipient and tablet formulation comprising active medicament; polysaccharide gum, *e.g.*, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, or carboxymethyl cellulose; and diluent, *e.g.*, microcrystalline cellulose, dextrose, or mixtures thereof (columns 6-8). The dissolution time for the active medication is within about 3.5-5 hours (column 9, lines 43-60). Hence, it would have been prima facie obvious for one of ordinary skill in the art to modify the pharmaceutical preparation of Bertini in view of the teaching of Baichwal, because the cited references teach the advantageous results in the use of cellulose and dextrose or maltodextrin. The expected result would be a useful excipient composition, which can

be blended with a wide variety of active medicaments for sustained/controlled release oral dosage form.

Claims 1, and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al. US 5,470,581.

Grillo teaches dry powder film coating composition for pharmaceutical tablet, the coating comprising from 4-90% cellulosic polymer, and from 5-78.5% maltodextrin (column 2, and abstract). The weight ratio of cellulosic polymer to maltodextrin is 3:7 (id).t is the examiner's position that it would have been obvious for one of ordinary skill in the art to modify Grillo's composition with the expectation of at least similar result, because Grillo obtains the same formulation desire by the applicant, i.e., mixture of cellulosic polymer and maltodextrin as dry powder edible film coating composition for use in pharmaceutical tablet (abstract).

Claims 21-23, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Baichwal et al. US 5,128,143.

Grillo is relied upon for the reason stated above. Grillo does not teach the sustained release time period.

Baichwal teaches sustained release excipient and tablet formulation comprising active medicament; polysaccharide gum, *e.g.*, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, or carboxymethyl cellulose; and diluent, *e.g.*, microcrystalline cellulose, dextrose, or mixtures thereof (columns 6-8). The dissolution time for the

active medication is within about 3.5-5 hours (column 9, lines 43-60). Hence, it would have been prima facie obvious for one of ordinary skill in the art to modify Grillo's coating composition for pharmaceutical tablet in view of the teaching of Baichwal, because the cited references teach the advantageous results in the use of cellulose and dextrose or maltodextrin. The expected result would be a useful excipient composition, which can be blended with a wide variety of active medicaments for sustained/controlled release tablet dosage form.

Claims 2-6, 33, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al., and Lord et al. US 6,417,227.

Bertini is relied upon for the reasons stated above. Bertini teaches the use of medicament, but silent as to the teaching of the specific medicament being claimed.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Lord's formulation using the excipient in view of the teaching of Bertini, because the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 2-6, 33, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Lord et al. US 6,417,227.

Grillo is relied upon for the reasons stated above. Grillo teaches the use of medicament, but silent as to the teaching of the specific medicament being claimed.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Lord's formulation using the coating excipient in view of the teaching of Grillo, because the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 14, 15, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., in view of Lord et al., and Grain processing Corporation.

Grillo and Lord are relied upon for the reasons stated above. The references are silent as to the teaching of the claimed maltodextrin.

Grain processing corporation teaches maltodextrin, such as Maltrin® having no protein, fat, or fiber, which is commonly used in consumer products as dry mixes (pages 1-2). Hence, it would have been obvious for one of ordinary skill in this art to modify Grillo's maltodextrin using Maltrin® in view of the teaching of Grain processing

Corporation. The reason for this modification is to obtain an excellent dry powder edible film coating composition for use in pharmaceutical, food and confectionery forms.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Baichwal et al., and Lord et al.

Regarding to claims 24-28, Grillo and Baichwal do not teach the specific active agent.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the compositions of Grillo and Baichwal with the active agents in view of Lord's teaching to obtain the claimed invention, since the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Bertini et al.

Grillo is relied upon for the reasons stated above. Grillo does not teach the claimed cellulose polymer.

Bertini teaches excipient composition for controlled release oral dosage form comprising maltodextrins and powdered cellulose. Although Bertini does not teach the

polymerization degree range of cellulose, it is the examiner's position that, it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable cellulose powder to obtain a desirable dry powder coating composition.

Response to Arguments

Applicant's arguments filed 11/17/03 have been fully considered but they are not persuasive. The examiner maintains the original rejections.

Applicant argues that the present claim 1 is directed to mixtures and does not permit "the film forming around the dosage form". Nonetheless, the phrase "upon mixing with a bioactive substance in an orally administered substance" does not exclude the film forming composition taught by Grillo. It is noted that the claimed combination of "cellulose and maltodextrin" are used as an excipient. Nowhere in the claims exclude the excipient from being in the coating, and nowhere in the claims limit the placement/location of the excipient.

Applicant further alleges that Grillo requires the use of a plasticizer, such as polyethylene glycol and water. Contrary to the applicant's argument, the transitional phrase "comprising of" s inclusive or open-ended and does not exclude additional, un-recited elements.

Applicant argues that there is no suggestion to combine Grillo and Baichwal. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is

some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Baichwal is relied upon solely for the teaching of the sustained release profile.

Applicant argues that there is no suggestion in either reference that the proposed modification, taken from Baichwal, would make Grillo satisfactory for its intended purpose of applying "coatings" of achieving coatings or coating films that have the desired properties taught by Grillo. Therefore, the proposed combination does not teach all the recited limitations in independent claim 21. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that applicant is not merely claiming the use of cellulose and maltodextrin in any form in orally administered compositions. Rather, it is by distributing cellulose and maltodextrin throughout orally administered specimen that results in the advantages of sustained release compositions that gel upon ingestion and thereby prevent direct contact between a substantial amounts of the administered medicament are obtained. Contrary to the applicant's argument, the features upon which applicant

relies (i.e., compositions that gel upon ingestion and thereby prevent direct contact between a substantial amount of the administered medicament are obtained, or protect a stomach wall from direct contact with a medicine or supplement) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Grillo is focused on coatings and coating films. Lord on the other hand is concerned with coating or enteric coating to prevent the cetyl myristoleate from being released in the stomach. Therefore, the proposed combination would destroy the intended purpose of Lord and is not permissible. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case,

Lord is relied upon solely for the teaching of the claimed medicament, which can be in a delayed dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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